Supplemental PMA application for a **bilateral** deep brain neurostimulation system to have the trade name of the "Medtronic Activa Parkinson's Control Therapy." This supplemental application was subject to the same standards as the initial PMA application. This bilateral Medtronic system employed the same components as the Activa Tremor Control system, but with bilateral implantation. (*See* Summary of Safety and Effectiveness Data For A Supplemental Premarket Approval Application which can be found at the FDA's web site at www.fda.gov/cdrh/pdf/p960009.pdf) Medtronic did not receive FDA approval of its supplemental PMA application for its bilateral system until January 14, 2002. As an explicit part of this approval, the first contraindication listed for the recipients of this system provided:

> **Patients exposed to diathermy**. Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (now all referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. (www.fda.gov./crdh/pdf/p960009.pdf)

As part of its obligations under the MDA, and as a condition for its continued approval of both its Activa Tremor Control System and its Activa Parkinson's Control Therapy System, Medtronic was required to have contact information regarding all recipients of the devices available to it, including their phone number, so that Medtronic could contact them quickly if serious problems arose with their devices. Under the FDA regulations at 21 CFR 814.39(d)(1) and (2), Medtronic was allowed to immediately send out warnings of serious dangers with its products of which it became aware, without prior FDA approval. The FDA

encouraged the issuance of such warnings and relied upon the good faith of manufacturers in doing so. (*See* Appendix C, Letter of Opinion of Casper E. Uldriks, Special Assistant to the Director, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration)

On or about January 10, 2001, Medtronic became aware that a recipient of its Activa Parkinson's Control Therapy became comatose while receiving diathermy treatment as part of a routine dental proce ure and died shortly thereafter. Medtronic has admitted that the course of this patient is accurately reflected in an article published in Neurology 2001; 56: 1384-1386 (published in May 2001) describing the experience and treatment of this recipient. This article concluded:

> Our case illustrates that exposure of the IPG, leads, or electrodes (of the Medtronic bilateral deep brain stimulation system) poses a danger for tissue damage in the region of the electrodes. Further definition of other potentially dangerous interactions is needed. For now, it is important for the physicians to be aware of this adverse event and to educate their patients to avoid exposure to RF diathermy in the vicinity of the IPG's, leads, and electrodes.

On May 18, 2001, four months after Medtronic had learned of the danger of diathermy to the implants, Medtronic sent a letter to recipients of its deep brain stimulation systems, by ordinary mail, informing them of the dangers of severe injury or death from the exposure to diathermy. At the same time, Medtronic warned recipients of multiple other kinds of Medtronic implants of the common danger from the induction of an electrical current in the implants through exposure to diathermy. Medtronic sent these warnings

without prior FDA approval as was authorized by 21 CFR 814.39(d)(1) and (2).

On May 17, 2000, Jack McMullen underwent the surgical implantation of a Medtronic bilateral deep brain neurostimulation system as a treatment for the symptoms of Parkinson's disease. As a result of the implantation of this bilateral deep brain neurostimulation system, Jack experienced a tremendous remediation of his Parkinson's symptoms, virtually returning him to a fully functional life. At that time, Medtronic's application for a PMA supplement for bilateral implantation had not been approved by the FDA.

On March 13, 2001, Jack McMullen (not having been warned of any dangers from exposure to RF diathermy) underwent a dental procedure involving the use of an electrosurgical instrument which utilized radio waves to heat or cauterize. Shortly following this procedure, Jack McMullen experienced a tremendous exacerbation of his Parkinson's symptoms.

Medtronic has admitted that it had been in possession of Jack's telephone number in its device registration system since May 23, 2000. Medtronic has further admitted that it made no effort to contact Jack McMullen until May 18th of 2001 when it voluntarily – and without prior FDA approval – sent safety alert letters to both doctors and patients.

According to a letter of opinion from Casper E. Uldriks, Special Assistant to the Director, Office of Compliance, Center for Devices and Radiologic Health, (Appendix C), no FDA requirements prohibit a voluntary warning by a manufacturer to users of its products associated with a report made to the Agency pursuant to Section 519 of the Act. To the contrary, the agency's enforcement policy described in 21 CFR Part 7 would urge manufacturers to initiate a

voluntary removal or correction of marketed violative products.

Dr. Leslie A. Geddes, Ph.D., and Distinguished Professor Emeritus in the Department of Biomedical Engineering at Purdue University, having reviewed the case materials, submitted an affidavit that it was his expert opinion that:

> The exposure of the Medtronic bilateral deep brain neurostimulation system to radio frequency electrosurgical current from the MD-9 resulted in the induction of electrical current in the leads and electrodes of the Medtronic system resulting in heating the electrodes beyond the temperature sufficient to cause damage to the portions of the brain in the immediate area of the electrodes.

Following the diversity removal of this action from the State of Indiana Circuit Court to the District Court, cross motions for summary judgment were filed. On September 15, 2004, the District Court granted Medtronic's motion (and denied the McMullens' motion) on the basis of federal preemption of plaintiffs' state law cause of action by the MDA. The district court stated in its order (*See* Appendix B):

> A jury finding of failure to warn would be premised on the fact that the labels, warnings, and documentation provided to both Mr. McMullen and his physician were not written in a particular way, did not contain certain information, or that Medtronic had additional duties, beyond those spelled out in federal regulations pertaining to the Activa. This would be equivalent to a state regulation imposing specific warning requirements to the Activa.

In doing so, the district court failed to appreciate that the plaintiffs were asserting a post-sale duty to warn of newly discovered dangers which were fully consistent with existing federal requirements. And while the Seventh Circuit did recognize that the plaintiffs were asserting a post-sale duty to timely warn cause of action, that court's analysis was also flawed. The Seventh Circuit, through Chief Judge Flaum, correctly observed that the FDA not only required Medtronic to continually track each Class III neurostimulation implant patient, but that:

> Medtronic also had a continuing obligation to report to the FDA any adverse events which would reasonably suggest that the device caused or contributed to a death or serious injury. *See* 21 U.S.C. § 360i; 21 CFR §§ 803.10((c). 421 F.2d 488.

Chief Judge Flaum, however, then proceeded to state, citing 21 CFR § 814.39(a):

> If Medtronic believed that a warning different from the one approved by the FDA was appropriate in light of an adverse event, it was required to seek FDA approval of any proposed changes. *See* 21 CFR § 814.39(a).

In fact, CFR 814.39(d)(ii) permitted Medtronic to issue new warnings to recipients without any prior FDA approval if such warnings advised the patients of new danger associated with the devices. The issue here is not that the new warning was insufficient. The issue is whether the new warning, sent by Medtronic four months after it learned of the danger, was timely. The larger issue, and the basis of this writ, is whether the state law requirement to timely warn parallels and is consistent with both CFR 814.39 and the intent of the Medical Device Act.

REASONS FOR GRANTING THE PETITION

1. Review is warranted to resolve the conflict among the circuit courts and various state courts regarding the preemptive effect of the MDA on state common law causes of action. Due to the widely varying interpretation of the Court's decision in *Lohr v. Medtronic, Inc.* by lower courts, this is a issue on which this Court's guidance is urgently needed.

In the seminal decision of *Lohr v. Medtronic*, 518 U.S. 470 (1996), this Court expressed a unanimous view that: "Section 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements." (O'Connor concurring in part and dissenting in art. 518 U.S. 513). Following the *Lohr* decision, however, various federal courts and several state courts issued a myriad of contradictory opinions regarding what the *Lohr* decision indicated in terms of preemption. Several circuits, including the 3rd, 5th, 6th, 7th, 8th and 9th, have opined that virtually all state law causes of action are preempted by the Medical Device Act. These circuits premise their holdings on the basis that the PMA approval process is a stringent examination of the medical device in question and that the conditions for approval are, in essence, requirements which preempt most state law actions. This interpretation is illustrated in the holding of *Mitchell v. Collagen, Corp.*, 126 F.3d 902 (7th Cir. 1997). *Mitchell* stated at p. 913: "The PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling." The *Mitchell* court further held that such approval was product-specific and the conditions imposed rose to the level of requirements, thereby preempting state law claims.

In marked contrast, the 10th and 11th circuits have taken a restrictive view of the preemption afforded by the Act,

holding that PMA conditions for approval are not device specific but rather common elements of all PMA approvals and, therefore, do not rise to the level of requirements. In *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (which examined various causes of action based on the identical product held preempted in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000)) the court stated:

> The "Conditions of Approval" document enclosed with the letter that noted the FDA's approval of the 4004M PMA application sets forth rules and regulations generally applicable to all devices approved through the PMA process. For example, the "Conditions of Approval" remind Medtronic of its obligation to provide post-approval reports, to refrain from changing the device without FDA approval, and to report adverse reactions and device defects.

Further, state courts have differing views of the scope of preemption provided by the Act. The Supreme Court of Illinois, at odds with the 7th Circuit holding in *Mitchell v Collagen*, stated in *Weiland v. Telectronics Pacing Systems, Inc.*, 188 Ill.2d 415, 721 N.E.2d 1149 (1999) at p. 420:

> TPSI's interpretation of section 360k would have "the perverse effect of granting complete immunity from design defect liability to an entire industry that in the judgment of Congress, need more stringent regulation 'in order to provide for the safety and effectiveness of medical devices for human use." *Lohr* at 487.

The Illinois Supreme Court in *Wieland,* addressing the PMA approval process went on to state at p. 420:

> The Premarket Approval process allows the FDA to assure the minimal safety of medical devices which are marketed for human consumption; the premarket approval process simply does not address the appropriate standards of liability once the medical device enters the market. *Goodlin* 167 F.3d at 1378. There is simply no support for TPSI's assertion that Congress intended to preempt almost all state common law claims against the manufacturers of medical devices which receive premarket approval from the FDA. *Goodlin* 167 F.3d at 1378. In the absence of a clear and manifest Congressional intent to create the sweeping preemption of state common law claims suggested by TPSI, we hold that the FDA's premarket approval of a Class III medical device does not establish a specific federal requirement which preempts plaintiff's state common law claims.

It is vital that this Court clarify under what circumstances courts can dispose of otherwise meritorious cases on the basis that such cases are preempted by the Medical Device Act. The class of people affected by these decisions are already burdened by great physical infirmities. Denying them the right to redress for wrongs committed against them, such as a failure to timely warn as in this case, has even more severe consequences to this already disadvantaged group. Further, preemption of remedies or redress must have some overriding national importance as its foundation since such preemption is a serious infringement on this group's state constitutional rights.

It is also vital that this Court delineate the scope of preemption insulating medical device manufacturers under the Medical Device Act since such preemption is a severe intrusion on state sovereignty affecting both the citizens and

police powers of the states. As this Court stated in *Lohr* at 485:

> First, because the States are independent sovereigns in our federal system we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly those in which Congress has "legislated . . . in a field which the States have traditionally occupied," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947), we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

In *Lohr*, this Court set an analytical framework for determining the pre-emptive effects of the Medical Device Act. The principles of *Lohr* were recently revisited by this Court in *Bates v. Dow Agrosciences LLC*, 03-388 (2005). In *Bates*, this Court adopted a "parallel requirement" reading of the pre-emption provision there at issue which it found to be directly analogous to section 360 ddressed in *Lohr*. The Court stated:

> The "parallel requirements" reading of § 136v(b) that we adopt today finds strong support in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In addressing a similarly worded pre-emption provision in a statute regulating medical devices, we found that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."

This Court further determined that any state rules that are consistent with federal requirements are not preempted.

This principle of "parallel requirements", and the role of the FDA, was addressed by Justice Breyer in his concurring opinion in *Bates*:

> In *Medtronic v. Lohr* (citation omitted), I pointed out that an administrative agency, there the Food and Drug Administration, had the legal authority within ordinary administrative constraints to promulgate agency rules and to determine the pre-emptive effect of those rules in light of the agency's special understanding of "whether (or the extent to which) state requirements may interfere with federal objectives." *Id.*, at 506 (opinion concurring in part and concurring in judgment). The EPA enjoys similar authority here. * * * As suggested by *Medtronic*, the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements.

Jack and Barbara McMullen submit to this Court that the sweeping interpretations of preemption under this Act, which several circuits have implemented, are dangerously close to unconstitutionally infringing on state sovereignty and the state rights of the people who receive these devices. Although Medtronic has argued in this case that the need for uniformity is a pressing concern, that argument must be weighed against the intended purpose of this Act. The intent of the Medical Device Act was never to afford protection from liability for individual medical device manufacturers. Rather, the protection afforded by the Act lies with the patients who have these devices implanted in their bodies.

It is important that this Court address the scope of preemption under the MDA not only because such preemption affects a large class of persons with physical impairments, but also because the current differing interpretations of that scope leaves the law unsettled in this important area.

2. Review of this case is essential to determine whether Medtronic's post-sale duty to warn of new dangers to patients with Class III medical devices is preempted by FDA approval of those devices, and whether that approval absolves Medtronic of any continuing duty to warn of new and serious dangers of which it becomes aware after the devices are implanted in the patients.

The McMullen's brought the instant action as a state-law post-sale duty to timely warn, an action seeking to enforce parallel federal requirements. The essence of Medtronic's preemption argument is that although Medtronic became aware of a new and serious danger to recipients of its deep brain stimulation systems, it was neither required to – nor permitted to – notify recipients of those systems of that danger. Both the district court and the 7th Circuit, erroneously following this argument, dismissed the McMullen's post-sale duty to timely warn action as attempting to impose a requirement additional to those of the federal regulatory scheme. This ruling totally ignores the tracking and reporting requirements under the Medical Device Act and directly contradicts the purpose and intent of those provisions.

The real issue is whether any of the regulations under the Act prevented Medtronic from warning recipients of its deep brain stimulation systems. The simple answer is no. The intent of the rules and regulations is to track the implant systems so that the recipients of those systems can be warned

of previously unanticipated dangers. Further, the flawed logic of both the 7th Circuit and district court is best demonstrated by the fact that *Medtronic did, without prior FDA approval, warn those recipients of the dangers of diathermy. It simply did not do so in a timely manner.*

In *Lohr v. Medtronic*, 518 U.S. 470, 235 L. Ed. 2d 700, 116 S. Ct. 2240 (1996). Part V of the majority opinion approvingly cited 21 CFR § 814.39 (in footnote 16) which allows device manufacturers to warn without prior FDA approval in situations involving potential serious injury. Moreover, FDA regulations provide for strict tracking procedures for Class III medical devices so that users may be expeditiously warned of potential dangers.

The clear language of the tracking requirement of CFR 821.1 mandates that manufacturers of Class III medical devices track the recipients of those devices to their home addresses in order to notify them of serious dangers. The relevant portion reads:

> Sec. 821.1 Scope
>
> (a) The regulations in this part implement section 519(e) of the Federal Food, Drug and Cosmetic Act (the act) which provides that the Food and Drug Administration may require a manufacturer to a adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and the FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences. . . .
>
> (b) these regulations are intended to ensure that tracked devices can be traced from the device

> manufacturing facility to the person for whom the device is indicated, that is, the patient.
>
> Effective tracking of devices . . . is necessary for the effectiveness of remedies prescribed by the act, *such as patient notification* . . . (emphasis added)

Further, the FDA approvals of both Medtronic's Activa Tremor Control Therapy and Activa Parkinson's Control Therapy systems are expressly conditioned on the tracking requirements. The FDA approval letter of the Activa Tremor Control Therapy system to Medtronic states:

> Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990) manufacturers of certain devices must track their products to the final user or patient so that the devices can be located quickly if serious problems are occurring with the products.

It is clear that Medtronic was required to track the device implanted in Jack McMullen. It is also clear that CFR 814.39 (approvingly cited by *Lohr*) allowed Medtronic to issue a "safety alert" without any prior FDA approval.

> Section (d) (1) of 21 CFR 814.39 states:
>
> After FDA approves a PMA, any change described in Paragraph (d)(2) of this section that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under Sec. 814.17 of a written FDA order approving the PMA supplement. . . .

Section (2) states, in pertinent part:

> The following changes are permitted by paragraph (d) (1) of this section:
>
> (i) Labeling changes that add or strengthen a contraindication, warning, precaution or information about an adverse reaction.

It is evident from these sections alone that both courts were in error in holding that subsequent warnings of new dangers were new requirements or simply allegations of inadequate warnings. Such rationale flies in the face of the regulations and their purpose to protect the public from unsafe drugs and medical devices.

In the regulatory scheme established by the FDA regulations Section 814.39 would be rendered meaningless if manufacturers do not have to warn of newly discovered dangers associated with their products. As Casper Uldriks, Special Assistant to the Director in the Office of Compliance in the Center for Devices and Radiological Health, stated in the FDA letter of opinion submitted in relation to this matter (*See* Appendix C):

> I know of no text in the Act's section on Records and Reports on Devices that prohibits a voluntary warning associated with a report made to the Agency pursuant to section 519 of the Act. To the contrary, the agency's enforcement policy described in 21 CFR Part 7 would urge manufacturers to initiate a voluntary removal or correction of marketed violative products.

Mr. Ulriks further emphasized that "The goals of the regulation are to detect and correct problems in a timely manner."

Medtronic has argued before this Court that all common law claims brought by any plaintiff against a medical device manufacturer like itself are preempted. As this Court responded at page 716 of *Lohr*

> Medtronic's argument is not only unpersuasive, it is implausible. Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device.

More importantly, this Court emphasized in *Lohr* that state-law actions which encourage compliance with federal regulations are not preempted. Further, even the *Mitchell* court's analysis of the *Lohr* opinion which concluded that certain state law actions can impose requirements different from the FDA PMA approval stated, regarding the Supreme Court's decision in *Lohr*, at p. 908:

> The unanimous Court also held, to the extent that a common-law action mirrors the FDA regulations, it would not be preempted. Nothing in the MDA, held the Court, denies the state "the right to provide a traditional damages remedy for violation of common-law duties when those duties parallel federal requirements . . ." the addition of a damages remedy likewise does not create a preemption situation. It merely provides an additional reason for the manufacturer to comply with the federal regulations.

Medtronic asks this Court to ignore, as Medtronic does, the post-market surveillance requirements of the FDA regarding Class III medical devices. Such requirements indicate that Medtronic had a continuing duty to warn – a duty required and encouraged by the Medical Devices Act.

Although the District Court spent a great deal of time discussing the rigors of the PMA approval process, such discussion is not relevant to the instant case. This case deals with the timeliness of the duty to warn of new danger as they become known which is part of the conditions of continued approval from the FDA. Such state cause of action is not preempted by the Act or the requirements promulgated by the FDA. Instead, such action encourages compliance with those regulations.

If the purpose of the MDA is to protect the patients with these devices in them, it cannot be seriously argued that Medtronic, the medical device manufacturer in this case, is immune from liability from its failure to timely warn Jack McMullen of a danger which has ruined his life.

The issue of a continuing duty to warn has not really been directly addressed by the circuit courts. There is no incompatibility whatever between the requirements of the FDA and a common law post-sale duty to *timely* warn action. Rather, the common law causes of action and the FDA requirements have a commonality – common sense. The common law actions provide a remedy when there has been a violation of a post-sale duty to *timely* warn once a danger of a serious injury becomes known.

The 7th Circuit's ruling in this case produces the absurd result that, since CFR 814.39 only permits Medtronic to timely warn but doesn't require Medtronic to do so, Medtronic can never be held liable for its failure to warn of any new dangers associated with its medical devices no matter how egregious its conduct. Such result flies directly in the face of the purpose of the Act and the tracking regulations promulgated under it. This Court needs to address this important issue regarding the manufacturer's continuing duty to keep people advised of serious dangers associated with the devices implanted in them.

CONCLUSION

For all the foregoing reasons, petitioners respectfully that the Supreme Court grant review in this matter.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT DECIDED AUGUST 26, 2005

In the
UNITED STATES COURT OF APPEALS
for the Seventh Circuit

No. 04-3678

JACK McMULLEN and BARBARA McMULLEN,

Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,

Defendant-Appellee.

Argued June 10, 2005—Decided August 26, 2005.

Before FLAUM, *Chief Judge*, and POSNER and KANNE, *Circuit Judges.*

FLAUM, *Chief Judge.* Plaintiffs-appellants Jack and Barbara McMullen filed suit against defendant-appellee Medtronic, Inc., alleging state-law claims arising out of the implantation of two of Medtronic's Activa Tremor Control Systems ("Activas") in Jack McMullen's brain. The district court granted summary judgment in favor of Medtronic on the ground that the McMullens' claims are preempted by federal requirements imposed by the Food and Drug Administration ("FDA") pursuant to the Medical Device

Amendments ("MDA"), 90 Stat. 539, to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C § 301 *et seq.* The McMullens appeal, and for the reasons stated herein, we affirm.

I. Background

The Medtronic Activa is classified under the MDA as a Class III medical device, which means that it "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). Before a Class III device may be introduced into the market, the manufacturer must provide the FDA with a " 'reasonable assurance' that the device is both safe and effective." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (quoting § 360e(d)(2)). The process by which the FDA decides whether a manufacturer has provided a "reasonable assurance," known as the "premarket approval" or "PMA" process, is a rigorous one. *Id.* Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA thoroughly reviews. *Id.* Approval by the FDA may constitute acceptance of such things as the product's design, testing, intended use, manufacturing methods, performance standards, and labeling. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir.1997).

In 1997, following a full PMA review, the FDA approved Medtronic's Activa for use in the suppression of tremors in patients diagnosed with Parkinson's Disease. The Activa is

composed of three parts: the implantable pulse generator ("IPG"), which is the power source; the lead, which is a thin insulated wire with a series of tiny electrodes at one end; and the extension, which connects the IPG to the lead. Electrical impulses are conveyed through the device, electrically stimulating areas of the brain that control movement and muscle function.

Pursuant to its approval, the FDA required Medtronic to track the name and contact information of patients implanted with the Activa. The FDA also required Medtronic to list specific warnings regarding "electrocautery" and "diathermy"[1] in its manuals for physicians and patients. The patient manual was required to state:

> Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.
>
> Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site.

* * *

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1. While neither party provided precise definitions of these terms, it appears that "electrocautery" is the burning or searing of tissue by means of an electrically heated instrument, and "diathermy" is therapeutic local heating by means of passing electric currents through tissue. The distinction between the two procedures is not important for the purposes of this case.

Appendix A

Diathermy treatments that are sometimes used for muscle relaxation may affect the neurostimulator output and/or damage its electronics.

In May 2000, Jack McMullen, who has been experiencing the symptoms of Parkinson's Disease since 1985, was implanted with two Activas, one on each side of his brain.[2] As a result of the bilateral stimulation, McMullen experienced an excellent remediation of his Parkinson's symptoms.

In January 2001, Medtronic learned of an anecdotal report involving a 70-year-old Parkinson's patient who had been implanted with an Activa. According to the report, a dentist treated the patient with diathermy following oral surgery. During the procedure, the patient was found unresponsive and it was determined that he was in a coma. The suspected cause was damage to brain tissue surrounding his Activa leads, induced by the diathermy.

About two months later, in March 2001, Jack McMullen underwent a dental procedure, which possibly involved diathermy or electrocautery. Thereafter, McMullen

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2. Before the district court, McMullen argued that he was not implanted with an Activa, but instead with a different Medtronic device called the Activa Parkinson's Control Therapy, which had not yet received FDA approval. The district court concluded that the record could not support this assertion. On appeal, McMullen still hints that he was not implanted with an Activa, but does not challenge the district court's conclusion directly. Accordingly, any arguments based on this factual assertion have been forfeited. *See Tyler v. Runyon*, 70 F.3d 458, 464- 65 (7th Cir.1995).

experienced a decline in the control of his Parkinson's symptoms. Despite further surgeries to replace components of the implanted Activas, the reduced symptom control continues to this day. McMullen suspects the cause to be damage to brain tissue surrounding the leads of his Activas.

Following further investigation of the January 2001 anecdotal report, Medtronic sent letters by mail to both physicians and patients in May 2001. Medtronic's patient letter stated:

> CONTRAINDICATION: Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, can cause tissue damage and can result in severe injury or death.
>
> Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and may require additional surgery to remove or replace parts of your implanted device. Injury or damage can occur during diathermy treatment whether your neurostimulation system is turned "on" or "off."

To make changes affecting the safety or effectiveness of a device that has gone through the PMA process, a manufacturer must submit a PMA Supplement for review

and approval by the FDA. *See* 21 C.F.R. § 814.39(a). Medtronic submitted a PMA Supplement, seeking FDA approval to market the Activa with a new, stronger warning, like that which was provided in the May 2001 patient letter. In June 2001, three months after McMullen's injury, the FDA approved the use of the new warning.

Thereafter, Jack McMullen and his wife, Barbara McMullen, filed a complaint in the Vermillion County Indiana Circuit Court alleging that Medtronic breached its post-sale duty to warn of dangers arising from the use of diathermy or electrocautery on a patient implanted with a Medtronic Activa. Specifically, plaintiffs assert that the January 2001 report about the 70-year-old Parkinson's patient triggered Medtronic's duty to immediately issue a new warning directly to patients about the increased risks of diathermy and electrocautery. The McMullens' complaint alleges that, as a result of the use of the electrical surgical instrument during his dental procedure, Jack McMullen suffered severe brain damage. In addition, Barbara McMullen alleges a derivative claim for loss of consortium.

Medtronic removed the case to the United States District Court for the Southern District of Indiana based on diversity jurisdiction, after which the parties filed cross-motions for summary judgment. Medtronic argued that plaintiffs' claims were preempted under the express preemption clause of the MDA and, in the alternative, that it was entitled to judgment as a matter of law on the merits of the McMullens' claims. The McMullens disputed Medtronic's claim of preemption and argued that the uncontroverted facts demonstrated that they were entitled to judgment as a matter of law on both of their claims.

The district court granted Medtronic's motion, holding that the post-sale failure to warn claim is preempted and that the derivative loss of consortium claim falls with it. The McMullens appeal, asking us to reverse the district court and direct it to enter summary judgment in their favor.

II. Discussion

We review the district court's grant of summary judgment de novo, viewing all facts and drawing all reasonable inferences in the non-moving party's favor. *Eisencorp, Inc. v. Rocky Mountain Radar, Inc.*, 398 F.3d 962, 965 (7th Cir.2005). Summary judgment is appropriate if the evidence presented by the parties "show[s] that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c).

At issue in this case is whether Jack McMullen's common-law claim against Medtronic for post-sale failure to warn is preempted by federal law. The principle of preemption arises from the Supremacy Clause of the Constitution which states that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI. "Pursuant to this authority, Congress may preempt state law." *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1246 (7th Cir.1997). "A federal law may preempt a state law expressly, impliedly through the doctrine of conflict preemption, or through the doctrine of field (also known as complete) preemption." *Boomer v. AT & T Corp.*, 309 F.3d 404, 417 (7th Cir.2002); *see also Hoagland v. Town of Clear Lake, Ind.*, 415 F.3d 693

(7th Cir.2005). The MDA contains an express preemption provision, under which, as we explain below, the state law that is the basis for McMullen's claim is expressly preempted. Accordingly, we do not address the doctrines of conflict and field preemption.

The MDA's preemption clause provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). This provision sets three conditions for preemption: (1) there must be a "requirement" that a state "establish[es] or continue[s] in effect, with respect to a device intended for human use"; (2) there must be a relevant federal requirement under the FDCA applicable to the device at issue; and (3) the state "requirement" must be "different from, or in addition to," the federal requirement. *See id.*

Here, the parties agree that the first condition is satisfied. McMullen states that his post-sale failure-to-warn claim arises either under the law of Indiana, where the injury

occurred, or under the law of Minnesota, where Medtronic's headquarters are located. We need not decide which law governs or the scope of the applicable common-law duty. It is enough to note that any state requirement that would provide a basis for McMullen's claim must have imposed on Medtronic a duty to provide an additional warning between January 2001, when Medtronic learned of the anecdotal report, and March 2001, when McMullen underwent the dental procedure and was injured. For the purposes of our preemption inquiry, we may assume that there is such a state-law duty and that McMullen's claim would be viable if not preempted. To the extent this duty exists and could be a basis for a verdict in favor of McMullen, it establishes a "requirement" with respect to the Medtronic Activa, a device intended for human use, and thus satisfies the first condition of preemption. *See Mitchell*, 126 F.3d at 910 (common-law causes of action may be "requirements" as the term is used in § 360k(a)); *see also Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 867, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (noting that a majority of the Supreme Court in *Lohr* agreed that common-law tort actions may be preempted under the MDA's preemption clause); *Bates v. Dow Agrosciences LLC*, __ U.S. __, 125 S.Ct. 1788, 1798, 161 L.Ed.2d 687 (2005) (holding that the term "requirements" in the preemption clause of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties").

There also is no dispute as to the second condition. To have preemptive effect under § 360k(a), a federal requirement must be specific to a particular device and relevant to the conduct that is the subject of the state requirement at issue.

Mitchell, 126 F.3d at 910 (citing *Lohr*, 518 U.S. at 500-01, 116 S.Ct. 2240). We have held that federal requirements specific to individual products are imposed through the PMA process. *Id.* at 911. Here, there were specific federal requirements as to the warnings given both before and after implantation of the Medtronic Activa. For example, the FDA approved and required the precise language of the diathermy/electrocautery warning given to McMullen, and, in its PMA approval letter, the FDA directed Medtronic to track all Activa recipients. Medtronic also had a continuing obligation to report to the FDA any adverse events which would reasonably suggest that the device caused or contributed to a death or serious injury. *See* 21 U.S.C. § 360i; 21 C.F.R. §§ 803.10(c), 803.50. If Medtronic believed that a warning different from the one approved by the FDA was appropriate in light of an adverse event, it was required to seek FDA approval of any proposed changes. *See* 21 C.F.R. § 814.39(a). These are relevant federal requirements limiting Medtronic's conduct as to the warnings it issued to Activa recipients. The second condition of § 360k(a) preemption is satisfied.

As to the third condition, the only one contested in this case, we must ask whether the state common-law duty underlying McMullen's claim would impose a requirement that is "different from, or in addition to," the relevant federal requirements. A claim that a manufacturer failed to provide an adequate warning at the time of sale would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA. Such a state-law claim would impose a requirement that was different from, or in addition to, the applicable federal requirements and would be preempted. *Cf. Mitchell*, 126 F.3d

at 913-14 (time-of-sale mislabeling claim preempted); *accord Horn v. Thoratec Corp.*, 376 F.3d 163, 177 (3d Cir.2004) (time-of-sale failure-to-warn claim preempted); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796-98 (8th Cir.2001) (en banc) (same); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir.2001) (same); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir.2000) (same); *Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir.1997) (same); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1374-78 (11th Cir.1999) (no preemption of common-law claims involving PMA-approved devices); *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir.1997) (no preemption of common-law claims where device undergoes the less rigorous "Investigational Device Exception" process).

McMullen, however, does not take issue with Medtronic's original warning. Rather, he claims that Medtronic violated a *post-sale* duty to warn, under which it was required to provide an additional warning in light of the January 2001 anecdotal report. Medtronic distributed just such an additional warning in May 2001, but McMullen contends that this was too late. He argues that Medtronic was obligated, under parallel state and federal laws, to send a "timely" additional warning, which he defines as one delivered sometime before his dental appointment in March 2001. If he is correct that there are both state and federal requirements to this effect, then the state requirements will not be different from, or in addition to, the federal requirements and McMullen's claim will not be preempted pursuant to § 360k(a). *See Mitchell*, 126 F.3d at 909 ("[T]o the extent a common law action mirrors the FDA regulations, it would not be preempted."); *Lohr*, 518 U.S. at 495, 116

S.Ct. 2240 ("Nothing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *see also Bates*, 125 S.Ct. at 1800-01 (relying on *Lohr* in holding that the phrase "in addition to or different from" in the FIFRA's preemption clause does not preclude states from providing remedies for violations of FIFRA's requirements). In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." *Bates*, 125 S.Ct. at 1804 (emphasis in original). State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law. *See id.*

McMullen points to two federal regulations as the basis for his contention that federal law creates a duty that is equivalent to the state-law duty underlying his claim: 21 C.F.R. § 821.1, which requires manufacturers to track recipients of devices; and § 814.39, which permits manufacturers to enhance warnings pending approval of a proposed change to an earlier-approved warning. Contrary to McMullen's contention, however, neither of these regulations, considered alone or together, imposed upon Medtronic a duty to issue an additional warning between January and March 2001.

Section 821.1 states that "[e]ffective tracking of devices from the manufacturing facility . . . to the patient is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device

recall (section 518(e) of the act)." Sections 518(a) and (e) of the MDA, codified at 21 U.S.C. §§ 360h(a) and (e), give the Secretary of Health and Human Services the discretion to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks, and to issue recall orders "[i]f the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death." Thus, the required tracking enables warnings to be issued and devices to be recalled if the Secretary decides that it is appropriate to do so. It does not impose on the manufacturer the obligation to make warning or recall decisions unilaterally, nor does it authorize the manufacturer to do so.

Section 814.39 permits a manufacturer to temporarily amend a warning pending FDA approval of the proposed changes. Once a temporarily amended warning has been approved, modified, or denied, the manufacturer must comply with the FDA's decision. *See Brooks*, 273 F.3d at 796. McMullen discusses at length the fact that Medtronic was "allowed" and "permitted" to issue an interim safety alert while awaiting approval of its amended warning. He argues that state common law requiring a post-sale warning merely "complements" the federal policy of allowing such warnings, and thus is not preempted. Recall, however, that the MDA's preemption clause provides that state requirements that are "in addition to" federal requirements are preempted. 21 U.S.C. § 360k(a). Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted. Because § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings

pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation.[3] Neither § 821.1 nor § 814.39 imposed on Medtronic a duty "genuinely equivalent" to the state common-law duty to provide an additional warning to McMullen between January and March 2001.

Because McMullen's claim based on the common-law post-sale duty to warn would impose on Medtronic a requirement that is in addition to federal requirements, we hold that the claim is preempted pursuant to 21 U.S.C. § 360k(a), and that the district court correctly granted summary judgment in favor of Medtronic. *Accord Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424-25 (6th Cir.2005) (holding that common-law post-sale duty to warn claim was preempted by requirements imposed through the PMA process). Accordingly, it also was proper for the district court to grant summary judgment in favor of Medtronic on Barbara McMullen's derivative claim for loss of consortium. *See Chambers*, 109 F.3d at 1244-45; *Mitchell*, 126 F.3d at 906; *accord Kemp*, 231 F.3d at 237. We need not reach the parties' arguments regarding possible alternative grounds for summary judgment.

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3. McMullen cites to an FDA letter of opinion stating that manufacturers are "urge[d] . . . to initiate a voluntary removal or correction of marketed violative products." An agency's urging, however, does not change a permissive provision into a mandatory one.

Appendix A

III. Conclusion

The district court's entry of summary judgment in favor of Medtronic is AFFIRMED.

A true Copy:

Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit

APPENDIX B — ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA, TERRE HAUTE DIVISION DATED SEPTEMBER 16, 2004

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

2:03-cv-005-LJM-WGH

JACK McMULLEN and BARBARA McMULLEN,
Husband and Wife,

Plaintiffs,

v.

MEDTRONIC, INC.,

Defendant.

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

This matter comes before the Court on Cross Motions for Summary Judgment filed by the Plaintiffs, Jack McMullen ("Mr. McMullen") and Barbara McMullen, husband and wife (collectively "the McMullens"), and Defendant Medtronic, Inc. ("Medtronic").

For the reasons stated herein, the Court GRANTS Medtronic's Motion for Summary Judgment, and DENIES the McMullens' Motion for Summary Judgment.

Appendix B

I. *BACKGROUND*

The McMullens filed a complaint against Medtronic on December 5, 2002, in Vermillion County Circuit Court, which Medtronic removed to this Court on January 8, 2003. The two-count complaint sets forth claims for a duty to warn based on Mr. McMullen's experience with the Medtronic Activa Tremor Control System ("the Activa"), and loss of consortium. The Activa is a prescription medical device that was bilaterally implanted in Mr. McMullen to help relieve him of symptoms associated with Parkinson's disease.[1] The McMullens allege that Medtronic was under a strict and nondelegable duty to warn recipients of the Activa of dangers posed to recipients both before and after the implantation of such devices. Medtronic did not issue warnings to Mr. McMullen of the danger of severe brain damage or death from diathermy/electrocautery treatments until May 2001, when it knew, or should have known, prior to that time that such treatments could result in injury. Comp. ¶¶ 12-15. Having not been warned, Mr. McMullen underwent a dental procedure involving the use of diathermy/electrocautery and suffered severe brain damage with resultant diverse, permanent, and disabling injuries. *Id.* ¶¶ 16-17. Plaintiffs further allege that Barbara McMullen, by Medtronic's

1. As summarized in Medtronic's Motion, "Parkinson's disease is a progressive, degenerative neurological disease arising from a reduced level of dopamine, a neurotransmitter that enables communications between the cells that control movement." Def.'s Br. Supp. at 6. Symptoms of Parkinson's disease include tremors (trembling), general slowness of movement, difficulty maintaining balance, and rigidity or stiffness in the limbs. *Id.* As will be discussed *infra*, McMullen had two Activa devices surgically implanted in his body to help alleviate the symptoms of his condition.

wrongful acts and omissions, has been deprived of Mr. McMullen's support, society, companionship, services, and consortium, and will continue to be so deprived. *Id.* ¶ 20. Medtronic moved for summary judgment as to both claims and the McMullens moved for summary judgment as to liability.

A. THE ACTIVA SYSTEM

Medtronic's unilateral Activa was first approved by the FDA in 1997 for the suppression of tremor in the upper extremity of patients diagnosed with essential tremor or Parkinsonian tremor. Def.'s Exh. 3. The unilateral Activa is composed of three distinct implanted products: (1) the implantable pulse generator ("IPG"), which is a power source for the System consisting of a sealed, oval-shaped metal container housing a special battery and programmable electronics that control the electrical charge the battery generates; (2) an extension, which is a thin insulated conductor connected to the IPG on one end and to the lead on the other end; and (3) the lead, which is a thin insulated wire with a series of tiny electrodes at one end that conveys electrical pulses from the IPG through the extension to the tissues in the brain where it stimulates a portion of the brain to suppress the disease symptoms. Def.'s Exh. 2, ¶ 30.

The Activa works by electrically stimulating the targeted structures in the brain that control movement and muscle function, a process also known as Deep Brain Stimulation ("DBS"). Def.'s Exh. 2, ¶ 16, Tab D at 3. Continuous stimulation of these areas blocks the signals between the brain and the rest of the body. In patients with tremor, these messages do not work correctly and cause the disabling motor

symptoms of Parkinson's disease. Stimulation from these systems may interrupt the messages that result in tremor and help suppress tremor. *Id.* As a result, many patients achieve greater control over their body movements.

On January 14, 2002, the Medtronic Activa Parkinson's Control System ("Activa Parkinson's") was approved by the FDA as a bilateral therapy—with electrodes implanted on both sides of the brain—for reducing additional symptoms of advanced Parkinson's disease. Def.'s Exh. 4. The Activa Parkinson's uses the same devices approved with the Activa. Def's Br. Supp. at 7.

B. THE PRE-MARKET APPROVAL PROCESS

A central issue in this case is whether the McMullens' state claims are preempted by the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 321-394 ("MDA"). Medtronic asserts that the McMullens' failure to warn and loss of consortium claims are preempted because the Activa went through a pre-market approval ("PMA") process by the Food and Drug Administration ("FDA"). A brief discussion of the MDA and PMA is necessary for a ruling on the instant motions.

In 1976, Congress enacted the MDA, which modified the FDCA to allow the FDA to regulate medical devices. The MDA divides medical devices into three categories, or classes. The most strict FDA regulation is reserved for Class III devices, defined as those which: (1) are to be used for supporting or sustaining human life or that are of substantial

importance in preventing impairment of public health; or (2) present a potential unreasonable risk of illness or injury. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). To market a Class III device within the United States, the manufacturer must either submit its product to the FDA for PMA, or qualify for one of two exceptions to this time-intensive regulatory review. The PMA process involves close scrutiny of the device by the FDA, and approval requires that the FDA conclude that it has received "reasonable assurances of [the device's] safety and effectiveness" from the manufacturer. *Id.* § 360c(a)(1)(C). To that end, manufacturers must provide the FDA with samples of the device, an outline of the device's components, a description of the manufacturing process, copies of the proposed labels, and various other information. *See* 21 C.F.R. § 814.20(b). The FDA then reviews such submissions for an average of 1,200 hours before either approving or disapproving the device. *See id.* §§ 812.1-.150; *see also Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir.1997).

A manufacturer may also gain regulatory clearance for a Class III device through one of two exemptions from the PMA process. First, the statute permits devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. *See* 21 U.S.C. § 360j(g)(1). This limited form of review is known as "premarket notification" or "the § 510(k) process," and averages only 20 hours of review as opposed to some 1,200 hours in the PMA process. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 479 (1996).

Second, devices representing innovative technology may be marketed under an investigational device exemption ("IDE"), an experimental regimen that allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1. Accordingly, a device operating under the IDE exemption need not comply with premarket approval requirements during the trial period. *See* 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812-813.

Should a manufacturer merely propose to modify a Class III device that already has received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submit the entire device for review. *See* 21 C.F.R. §§ 814.39, 814.80. The procedures applicable to a PMA Supplement are the same as those applicable to an original PMA, although the FDA only requires the manufacturer to provide that information necessary to support the proposed modifications. *See id.* § 814.3(g).

C. MR. McMULLEN'S EXPERIENCE WITH THE ACTIVA

Mr. McMullen has suffered from the symptoms of Parkinson's disease since 1985. Pl.'s Ex. 1. Mr. McMullen underwent a conventional drug therapy to control his symptoms. By 2000, his dosage requirements had risen to a point where his increasing symptoms could be only marginally controlled. Pl.'s Ex. 2. Mr. McMullen was implanted with two Activa systems, resulting in bilateral

stimulation to the subthalamic nucleus area of both the left and right sides of his brain. Pl.'s Exh. 3. As a result of the implementation of this bilateral DBS system, Mr. McMullen experienced an excellent remediation of his Parkinson's symptoms. Pl .'s Exh. 2.

Medtronic became aware in January 2001 that a user of an implanted DBS system had sustained potentially serious injury while undergoing routine diathermy following oral surgery. Pl.'s Exh. 8. On March 13, 2001, Mr. McMullen underwent a dental procedure involving the use of an electrical surgical instrument. Pl.'s Exh. 10. The parties dispute whether the procedure involved diathermy or electrocautery. *See e.g.*, Comp. ¶ 16; Def.'s Br. Supp. 1-3; Pl .'s Resp. at 2- 4. The McMullens' complaint asserts that, as a result of the use of the electrical surgical instrument during his dental procedure, Mr. McMullen suffered severe brain damage with resultant diverse, permanent, and disabling injuries. Comp. ¶ 17. On May 18, 2001, Defendant sent a letter to recipients of its deep brain stimulation systems, informing them of the dangers of severe injury or death from exposure to diathermy, approximately two months after Mr. McMullen's dental procedure. Pl.'s Exh. 11.

The parties do not dispute that the Activa Tremor Control System is a Class III medical device and that the Activa Tremor Control System went through the rigorous PMA process and was approved by the FDA on July 31, 1997, before it was marketed by Medtronic. *See* Pl.'s Exh. 4; Def.'s Exh. 3. Further, the parties agree that the Activa Parkinson's Control System was approved by the FDA as a bilateral therapy—with electrodes implanted on both sides of the

brain—for reducing additional symptom's of Parkinson's disease on January 14, 2002. Def.'s Exh. 4.

D. NATURE OF THE DEVICE IMPLANTED IN MR. McMULLEN

The parties expend great energy disputing the very nature of the DBS device implanted in Mr. McMullen on May 17, 2000. Medtronic correctly asserts it was a bilateral—and off-label—use of two Activas, which had received PMA approval on July 31, 1997. The McMullens claim the device was a single Activa Parkinson's that did not receive PMA approval under a supplemental application until January 14, 2002, barring preemption under § 360k, and is instead, governed by IDE regulations.

The McMullens call attention to an admission by Medtronic to support their claim that the device was an Activa Parkinson's. Pursuant to the Civil Justice Reform Act of 1990, 28 U.S.C. § 471 *et seq.*, Federal Rule of Civil Procedure 16 and 26, Southern District of Indiana Local Rule 16.1, and Order of the Court, the parties tendered a Case Management Plan ("CMP") to govern the proceedings in this case. In Defendant's Case Synopsis, Medtronic states: "On or about May 17, 2000, [Mr.] McMullen was implanted with an Activa® *Parkinson's* Control Therapy device." Case Management Plan ¶ II.B (emphasis added).

However, the medical records of Mr. McMullen and other uncontroverted evidence establish the device implanted in Mr. McMullen on May 17, 2000, was the Activa Tremor Control Therapy System, a Class III medical device approved

in July 1997 for marketing by the FDA under the PMA process. Pl.'s Br. Resp., Exh. A, Pl.'s Exh. 2 ¶ 19-24. Further, the record indicates that implantation of the Activa bilaterally was an off-label use of the device.[2] Pl.'s Br. Resp., Exh. B. Whatever semantic difference can be found in referencing a medical device under one trade name as opposed to another does not, in reality, change the nature of the device itself. In this particular instance, the Court finds the McMullens' argument unpersuasive. The record indicates that Mr. McMullen received two Activa devices that were approved by the FDA's PMA process. Medtronic, at worst, has made

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2. It is well established that the FDA does not prohibit "off-label" use of medical devices. *Minisan v. Danek Medical, Inc.*, 79 F.Supp. 790, 798 (N.D.Ind.1999) *citing Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690 (2d Cir.1994), *aff'd* 179 F.3d 725 (9th Cir.1999); *Weaver v. Reagen*, 886 F.2d 194 (8th Cir.1989). While the FDA controls the marketing and labeling of medical devices, it does not attempt to interfere with the practice of medicine. 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). The Supreme Court has emphasized that off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

Another district court has recently reached the conclusion that the PMA process results in preemptive, device-specific requirements in a case involving an off-label use of the device components at issue herein. *Davenport v. Medtronic, Inc.*, 302 F.Supp.2d 419 (E.D.Pa.2004).

an admission without a distinction that is immaterial to this case.[3]

II. *SUMMARY JUDGMENT STANDARD OF REVIEW*

Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This standard of review applies to cross

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3. Additionally, the McMullens argue that Medtronic had applied for, and been granted, an IDE for its Activa Parkinson's, and "[o]perating under an IDE imposes upon the device manufacturer a strict obligation to comply with IDE regulations imposing a strict duty to notify recipients of its device of serious dangers that become known" under various provisions of 21 C.F.R. § 812. Pl.'s Br. Supp. at 12. A complete and thorough search of Medtronic's clinical records verify that Mr. McMullen was never enrolled in any clinical studies of the Activa Parkinson's and further that the enrollment period for Medtronic's tremor control studies was closed before Mr. McMullen's implant surgery on May 17, 2000. Def.'s Br. Resp. at 3-4, Def.'s Exh. C. The McMullens have not presented any evidence to the contrary. Instead, they assert that Medtronic was obligated, having applied for an IDE for its bilateral Activa Parkinson's, to comply with IDE regulations not only with regard to the twenty-nine individuals taking part in the study, but also with regard to individuals, of whom Medtronic was aware had been implanted an equivalent system; a bilateral, off-label implant of two Activas. But under 21 C.F.R. § 812.2(a), IDE regulations apply only, with certain enumerated exceptions inapplicable to this case, to clinical investigations of devices to determine safety and effectiveness of which Mr. McMullen was not a participant.

motions for summary judgment. *See Int'l Bhd. of Elect. Workers v. Balmoral Racing Club, Inc.*, 293 F.3d 402, 404 (7th Cir.2002). We must view the admissible evidence supporting the motion in the light most favorable to the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The nonmovant must show through specific evidence that a triable issue of fact remains on the issues on which he bears the burden of proof at trial. *See Celotex*, 477 U.S. at 324. A genuine issue of material fact exists when the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *See Insolia v. Phillip Morris, Inc.*, 216 F.3d 596, 599 (7th Cir.2000). It is with these standards in mind that the Court addresses the instant motions.

III. *DISCUSSION*

The McMullens' two-count complaint sets forth claims for failure to warn and loss of consortium. In the instant motions, Medtronic asserts, and the McMullens' deny, that all of the McMullens' claims are expressly preempted by federal law and must be dismissed. Further, Medtronic argues that the McMullens' claims fail as a matter of law pursuant to applicable Indiana law in the absence of preemption. The McMullens' argue that their claims are not federally preempted because the Defendant was required to track implant recipients so each patient could be located if serious dangers were discovered and, alternatively, because Mr. McMullen was implanted with a device not approved by the FDA until after the injuries complained of. Further, the McMullens move for summary judgment as to liability under Minnesota law. The Court will now address these arguments in light of the applicable summary judgment standard.

Appendix B

A. PREEMPTION

Article VI of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, "any state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). With express preemption, a federal statute explicitly provides that it overrides state law. *Gracia v. Volvo Europa Truck, N.V.*, 112 F.3d 291, 294 (7th Cir.1997). "Whether federal law preempts a state law establishing a cause of action is a question of congressional intent." *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 907 (7th Cir.1997). Further, "[i]f the statute contains an express preemption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993); *Burlington N. & Santa Fe Ry. C. v. Doyle*, 186 F.3d 760, 790, 795 (7th Cir.1999).

Section 360k of the MDA expressly preempts specific state-law requirements regarding medical devices. The preemption provision states:

> [N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Furthermore, the legislative history of the MDA establishes that Congress intended extensive preemption of state law under § 360k. The House committee report for the MDA explains that the preemption provision was intended to be a "general prohibition on non-Federal regulation." H.R. REP. No. 853, 94th Cong., 2d Sess. 45 (1976).

In *Lohr*, the Supreme Court, in a plurality opinion, discussed the preemptive scope of Section 360k. 518 U.S. 470. The issue in *Lohr* was whether state tort claims were preempted because the FDA allowed a Class III pacemaker device to be marketed because it qualified as "substantially equivalent" to a preexisting device. *Id.* at 484. The Court stated the § 510(k) process for determining "substantial equivalence" "is by no means comparable to the PMA process," as the § 510(k) review "is completed in an average of only 20 hours." *Id.* at 478-79. In *Lohr*, the plaintiff received a pacemaker from a manufacturer. *Id.* at 481. The FDA allowed the pacemaker to be marketed because it was "substantially equivalent" to a preexisting medical device and was therefore exempted from the PMA process. *Id.* at 492. The plaintiff who received the device developed a

serious heart condition and required surgery after the pacemaker malfunctioned. *Id.* at 481. Plaintiff filed suit against the manufacturer alleging negligence and strict liability claims for defective design, failure to warn, and negligent manufacturing. *Id.*

The Court concluded that the plaintiff's claims were not preempted based on the fact that the "substantially equivalent" review process was not the type of specific federal requirement that triggered preemption. *Id.* at 501. In deciding the case, the Court offered guidance concerning when the MDA mandates that state law claims are preempted. First, there must be a federal requirement that is specific to the particular device. *Id.* at 500. Second, there must be a state law requirement that relates "to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* Finally, the state requirement must be "different from or in addition to" federal requirements. *Id.*

In his concurrence with the majority of the Justices, Justice Breyer stated that "the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, [as it would] pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). For the purposes of the instant case, the Court also emphasized that "nothing in *§ 360k* denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.*

Appendix B

The Seventh Circuit, in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir.1997), followed Justice Breyer's concurrence in Lohr, which suggests that § 360k(a) preempts some, but not necessarily all common law claims. *See Lohr*, 518 U.S. at 506 (Breyer, J., concurring). The *Mitchell* court found the *Lohr* disposition must be read "as acknowledging that at least some state-based common law causes of action must be considered 'requirements' as that term is employed in the MDA." *Id.* at 911. Further,

> the PMA process . . . can constitute the sort of specific federal regulation of a product that can have preemptive effect. During the PMA process, the federal government, it can truly be said, has "'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers.'"

Id. (*quoting Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.1997), *quoting Medtronic*, 518 U.S. at 501). In other words, the *Mitchell* court interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements. *Mitchell*, 126 F.3d at 913-14.

The *Mitchell* court found most of plaintiffs' claims against the manufacturer of collagen compounds, a Class III medical device, to be preempted. In analyzing the plaintiffs'

strict liability claim, premised on allegations that the device was an unreasonably dangerous product and that the manufacturer should have known of such unreasonable danger, the court reasoned that because approval of a product's design, testing, intended use, manufacturing methods, performance standards and labeling, a state court judgment premised on a contrary determination would constitute a requirement "different from, or in addition to" the standard required by federal authority and is preempted. *Id.* at 913. Likewise, a negligence claim was preempted to the extent that allegations were based on the theory that the manufacturer was negligent despite its adherence to the standards required by the FDA in its PMA process for a specific product. Finally, a mislabeling claim was preempted to the extent that the allegations involve a claim that a manufacturer had incurred liability under state law despite its conformity to the requirements of the PMA.

A "failure to warn" claim was not brought forth in that case and the Seventh Circuit has not directly addressed whether such a claim is preempted under § 360k.[4] However, the majority of circuits that have examined failure to warn claims have found federal preemption with respect to MDA devices. *See Horn v. Thoratec Corp.*, 376 F.3d 163, 177 (3rd Cir.2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir.2001); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir.2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir.2000); *Papike*, 107 F.3d at 742.

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4. A United States District Court for the Northern District of Indiana, in *Kozma v. Medtronic, Inc.*, 925 F.Supp. 602 (1996), like numerous other district courts in pre-*Lohr* decisions (citations omitted), held that a common law failure to warn claim is preempted under the MDA.

However, the Tenth Circuit, in *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir.1997), in an early post-*Lohr* decision, found that a common law negligent "failure to warn" claim was not preempted by the MDA. The *Oja* court reasoned that generic common law causes of action are not "requirements" developed specifically "with respect to" the medical device, and when stated without application to a particular product, they cannot be said to have been developed "in relation to" the medical device in question and thus are not subject to preemption. *Oja*, 111 F.3d at 789. The Seventh Circuit declined to adopt this approach and instead determined that the MDA preempts general common law claims to the extent that they interfere or conflict with specific federal requirements. *Mitchell*, 126 F.3d at 913-14.

B. PREEMPTION OF THE McMULLENS' CLAIMS

1. *Failure to Warn*

The Court must examine the tension between the McMullens' state common law "failure to warn" claim and § 360k(a). To the extent that this claim creates requirements that are in addition to, or different from, the federal requirements established by the FDA in approving the Activa, they are necessarily preempted by federally imposed PMA requirements under § 360k(a). *See Horn*, 376 F.3d at 177; Brooks, 273 F.3d at 796; *Martin*, 254 F.3d at 585; *Kemp*, 231 F.3d at 236. Put another way, State or local requirements are preempted when the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local

requirements applicable to the device different from, or in addition to, the specific FDA requirements. *See* 21 C.F.R. § 808.1(d). The *Lohr* Court emphasized that "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. As the Seventh Circuit recognized, to the extent that a complaint may be read as alleging the manufacturer failed to adhere to the standards of the FDA in the PMA, the claim would not be preempted." *Mitchell*, 126 F.3d at 913 n. 6. The *Mitchell* court also considered the preemptive scope of the MDA and has held that the PMA process results in preemptive, device-specific requirements. *Id.* at 911.

The FDA designated the Activa for tracking to the final user or patient so that devices can be located quickly if serious problems occur with those products as is required by regulation. *See* Pl.'s Exh. B; Pl.'s Exh. 5 (*citing* 21 C.F.R. § 821 *et seq.*). Additionally, through the PMA process, the FDA set forth specific warnings to be issued with the Activa. Medtronic provided the following FDA approved warnings to Mr. McMullen's physician in the Medtronic DBS implant manual:

> Electrocautery can cause temporary suppression of pulse generator output and or reprogramming of the pulse generator. If the use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pulse generator and lead as possible.

Def.'s Exh 2, Tab C at JMD 00021; Exh. 2, Tab G at JMD 00082; Exh. 2, Tab E at JMD 00119. Furthermore, Medtronic,

in accordance with the FDA's PMA process, provided the following warning with respect to diathermy in the DBS implant manual:

> The effects of diathermy on patients with an implanted neurostimulation system are unknown. Use of diathermy directly over an implanted lead or pulse generator is not recommended since internal components may be damaged.

Exh. 2, Tab C at JMD 00020; Exh. 2, Tab G at JMD 00083; Exh. 2, Tabe E at JMD 00120.

Medtronic also provided the following information directly to patients, including Mr. McMullen, in the Activa patient manual:

> Diathermy treatments that are sometimes used for muscle relaxation may affect the neurostimulator output and/or damage its electronics.
>
> * * *
>
> Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.
>
> Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site.

Def.'s Exh. 2, Tab D at JMD 00066.

Appendix B

A jury finding of failure to warn would be premised on the fact that the labels, warnings, and documentation provided to both Mr. McMullen and his physician were not written in a particular way, did not contain certain information, or that Medtronic had additional duties, beyond those spelled out in federal regulations pertaining to the Activa. This would be equivalent to a state regulation imposing specific warning requirements. Justice Breyer illustrated this principle in his concurring opinion in *Lohr* when he posited a situation in which an MDA regulation required that a hearing aid contain a 1- inch wire, but a state regulation required a 2-inch wire. That MDA regulation would preempt the state regulation. The same result ought to obtain, reasoned Justice Breyer, if a state tort action were to impose liability on the failure to have a 2-inch wire. Consequently, wrote the Justice, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Lohr*, 518 U.S. at 505 (Breyer, J., concurring).

While the McMullens couch their argument as Medtronic's failure to adhere to warning requirements set forth by the FDA through the PMA process, they, in actuality, argue the warnings required under the FDA were inadequate and seek to impose a standard of care or behavior imposed by a state-law tort action. The McMullens' claim is premised on the theory that Medtronic was under a strict and nondelegable duty to warn DBS devices before and after the implantation. Comp ¶ 12. The Plaintiffs base their claim on the federal requirement imposed by the FDA. Pl.'s Exh. B;

Pl.'s Exh. 5 (*citing* 21 C.F.R. § 821 *et seq.*). However, there is a logical disconnect between the federal regulation to track recipients of a device, and a duty, not set forth in any federal regulation pertaining to this device, to contact all recipients of that device upon the discovery of an adverse reaction in a recipient that, as it appears to be in this case, was the subject of product warnings approved by the FDA's PMA process. While the purpose of the tracking requirement is to prevent harm to individuals with Class III medical devices, it does not necessarily follow that the manufacturer is under a "strict and nondelagable" duty to inform recipients of all adverse reactions, or further to do so "within hours." The FDA retains continuing oversight over approved Class III devices. It requires manufacturers to report any deaths or serious injuries which result from the use of the product. *See* 21 C.F.R. § 803.1(a). The device at issue was thoroughly tested and otherwise scrutinized by the FDA, which approved Medtronic's application for PMA, thus allowing Medtronic to manufacture, market, and sell its DBS system as a prescription medical device. All aspects of the device were approved, including design, packaging, and warnings—which include warnings regarding diathermy and electrocautery procedures. The failure to warn claim asserted by the McMullens presupposes a duty "in addition to" the specific federal requirements imposed on Medtronic through the Activa's PMA process and approval.

Considering the Seventh Circuit's decision in *Mitchell*, and Justice Breyer's concurrence in *Lohr*, the Court aligns itself with the great weight of authority and finds federal preemption of the McMullens' failure to warn claims under the particular circumstances of this case. Even under these

unfortunate circumstances, the McMullens' state common law cause of action for a failure to warn is preempted under § 360k(a), and their subsequent arguments are rendered moot.[5]

2. *Loss of Consortium Claim*

The McMullens' Complaint includes a claim for loss of consortium. Based on the present state of the briefing, the Court will also grant the motion for summary judgment as to the loss of consortium claim that derives from the preempted claim.

V. *CONCLUSION*

For the foregoing reasons, the Court **GRANTS** defendant's, Medtronic Inc., Motion for Summary Judgment, and **DENIES** plaintiffs', Barbara and Jack McMullen, Motion for Summary Judgment.

IT IS SO ORDERED this 16th day of September, 2004.

s/ Larry J. McKinney
LARRY J. McKINNEY, CHIEF JUDGE
United States District Court
Southern District of Indiana

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5. Although the McMullens have asserted that Indiana law, under *Reed v. Ford Motor Co.*, 679 F.Supp. 873, 879 (S.D.Ind.1988), requires that a manufacturer or seller's duty to warn does not end at the time it places the product into the stream of commerce. Alternatively, the McMullens assert that under Minnesota law, a post-sale duty to warn also has been recognized, citing *Hodder v. Goodyear*, 426 N.W.2d 826, 833 (Minn.1988) (additional citations omitted).

APPENDIX C — LETTER FROM CASPER E. ULDRIKS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH TO JOHN PATRICK HEALY DATED JUNE 7, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 7, 2004

Mr. John Patrick Healy
29 South La Salle, Suite 640
Chicago, Illinois 60603

RE: Issuing Warnings for Class III devices

Dear Mr. Healy:

This is in response to your letter of June 1, 2004, inquiring about statutory provisions of the Federal Food, Drug, and Cosmetic Act (the Act) and related regulations promulgated under the Act's authority that would prohibit a manufacturer of a Class III device from issuing a warning, either before the Agency approves the premarket approval application (PMA) or after PMA approval based on postmarket regulatory programs.

Appendix C

Premarket Activities

Investigational Class III devices:

Class III devices are subject to PMA requirements of the Act. [21 U.S.C. 360e] Accordingly, a PMA must be supported by valid scientific evidence that incorporates extensive information collected from preclinical testing or studies, and human clinical trials to demonstrate the safety and effectives of the device. Clinical studies for Class III devices are subject to the statutory provisions identified in section 520(g) of the Act, [21 U.S.C. 360j(g)]. The regulatory requirements for conducting such studies are explained in 21 Code of Federal Regulations (CFR) Part 812. The sponsor (manufacturer) of a device that presents a significant risk to the patient is required to file an investigational device exemption (IDE) application and obtain FDA approval and Institutional Review Board (IRB) approval prior to conducted clinical testing. The FDA may re-evaluate, modify, suspend, or terminate and IDE based on its ongoing assessment of safety and effectiveness data collected during the clinical trials.

Original Premarket Review:

The FDA will accept and review statistically valid and reliable data conducted under the authority of regulations required for an IDE to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application. FDA will deny approval of an application for a device if the information provided demonstrates a lack of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling.

Appendix C

Supplemental Premarket Review:

A change in a PMA that affects safety or effectiveness requires the submission of a supplemental application for review and approval. [21 U.S.C. 360e(d)(6)(A)(i)] FDA may require additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness. [21 U.S.C. 360e(d)(6)(B)(ii)]

The IDE provisions of the Act serve to:

> . . . encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose. [21 U.S.C. 360j(g)(1)]

I know of no provision in the Act or IDE regulations that prohibit the sponsor from issuing a warning to individuals who are participating in the clinical study should adverse device effects arise. The regulatory provisions for monitoring an IDE clinical trail provide certain parameters for managing unanticipated adverse device effects. (21 CFR § 812.46) When an unanticipated adverse event occurs and the sponsor determines the adverse event presents an unreasonable risk to the subjects, the sponsor is directed to terminate as soon as possible all investigations or parts of the investigations that present that risk. The sponsor cannot resume the study without IRB and FDA approval. (21 CFR § 812.46(c))

Appendix C

Post Market Activities

Sponsor (manufacturer)
An approved PMA device is subject to extensive and continuing regulation by FDA. In addition to routine inspection by FDA, the PMA sponsor (manufacturer) is subject to a number of regulatory requirements, which include Medical Device Reporting (MDR) (21 CFR Part 803) and Reports of Corrections and Removals (C&R) (21 CFR Part 806). Reports generated by these post market reporting programs are subject to the statutory reporting requirements established by 21 U.S.C. 360i. The manufacturer, or its importer, of a device intended for human should make reports to FDA pursuant to 21 CFR 803 and/or 806 when they are aware of information that reasonably suggests that one of its marketed devices—

- may have caused or contributed to a death or serious injury, or

- has malfunctioned and that such device or a similar device marketed by them would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The Act defines serious injury as an injury that is

- life threatening,

- results in permanent impairment of a body function or permanent damage to a body structure,

- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

Such reports, whether submitted in accordance with 21 CFR Part 803 or Part 806, may not require that the identify of any patient be disclosed unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act.

21 CFR Part 806 — Reports of Corrections and Removals

Under 21 CFR 806, Medical Device Correction and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. A report must be made even if the event was caused by user error. A report is not required if the information has already been provided to FDA under MDR requirements (21 CFR Part 803) or Repurchase, Repairs or Replacement of Electronic Products (21 CFR Part 1004) or if the corrective or removal action was initiated by an FDA order under Medical Device Recall Authority (21 CFR Part 810). None of these reporting requirements prohibits the reporting of required information for marketed devices.

Manufacturers and importers must keep records of those corrections and removals that are not required to be reported to FDA. However, if a report is not required under 21 CFR

Part 806, the firm may voluntarily report under 21 CFR Part 7 and is encouraged to do so.

The definition of "risk to health" under 21 CFR 806 tracks the definitions of class I and class II recall in 21 CFR 7.3(m). Therefore, reports of corrections and removals are required for class I and class II recalls. Under 21 CFR 806, manufacturers and importers need not report events categorized as class III recalls under 21 CFR §7; only record keeping requirements would apply.

The following actions are exempt from the reporting requirements:

Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device,

- Market withdrawals,
- Routine servicing, and
- Stock recoveries.

Who must report

Manufacturers and importers are required to report a correction or removal of a product if it involves a risk to health. Only the person that initiates the correction or removal is required to report.

Appendix C

When to report

The report must be submitted to **FDA within 10 working** days from the time the firm initiates the recall. If there is not a "risk to health" involved, a report to FDA is not required, but the manufacturer or importer must keep a record of the recall.

What to Report - §806.10(c)

1. Registration number, date the report is made, sequence number (001, 002, etc.), "C" for Correction or "R" for Removal

2. Name, address, phone number, and contact person of the firm responsible for conducting the correction or removal.

3. Brand name and common name of the device and intended use.

4. FDA marketing status, i.e., 510(k), PMA, preamendment status and device listing number.

5. Model/catalog number, lot/serial number

6. Manufacturer's contact information (name, address, phone number, contact person) if different from item #2 above.

7. Description of event(s) and the corrective and removal actions that have been, and are expected to be taken.

Appendix C

8. Any illness or injuries that have occurred with the use of the device. If applicable, include any Medical Device Report (MDR) numbers submitted under 21 CFR 803.

9. The number of devices subject to the Correction or Removal.

10. Date of manufacture or distribution; expiration date or expected life.

11. Name, address, and telephone number of all consignees (domestic and foreign) and the dates and number of devices distributed to each consignee.

12. A copy of all communications regarding the correction or removal.

13. A statement as to why any required information is not available and a date when it will be submitted.

Where to report

Reports should be made to the FDA District Office in which the reporting facility is geographically located. Importers should contact the FDA District Office that covers their main port of entry.

Amendments

If, after submitting a report, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device,

the manufacturer or importer must amend the original report by submitting an amendment within 10-working days of initiating the extension of the correction or removal [21 CFR 806.10(d)]. The amendment should cite the original report number assigned, all of the information required by 21 CFR 806.10(c)(2), and any information required by 21 CFR 806.10(c)(3) through (c)(12) that is different from the information submitted in the original report. The manufacturer or importer must also state what required information is not readily available and a date for when it will be submitted.

Recordkeeping Requirements

The device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA must maintain records of the correction or removal. Records must contain the following information:

1. The brand name, common or usual name, classification, name and product code, if known, and the intended use of the device.

2. The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

3. A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

4. Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any follow-ups, and be reviewed and evaluated by a designated person.

Appendix C

5. A copy of all communications regarding the correction or removal.

The manufacturer or importer must retain all records for a period of two years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

Regulations

21 CFR 7 – Enforcement Policy

21 CFR 810 – Medical Device Recall Authority

21 CFR 806 – Medical Device Correction and Removals

21 CFR Part 803 - Medical Device Reporting

The MDR regulation provides a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner. Although the requirements of the regulation can be enforced through legal sanctions authorized by the *Federal Food Drug & Cosmetic (FFD&C) Act*, FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation.

Appendix C

The statutory authority for the MDR regulation is section 519(a) of the FFD&C Act as amended by the Safe Medical Devices Act (SMDA) of 1990. The SMDA requires user facilities to report:

- device-related deaths to the FDA and the device manufacturer;

- device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and

- submit to FDA on an annual basis a summary of all reports submitted during that period.

The user facility reporting section of SMDA became effective on November 28, 1991. Device manufacturers should familiarize themselves with the user facility requirements and read the guidance document entitled, "Medical Device Reporting for User Facilities." Since 1984, domestic manufacturers have been subject to the MDR regulation if they were required to register their establishment with the FDA. The new MDR regulation eliminates this link with registration. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturers, are now subject to the requirements of the MDR regulation, despite registration status.

The final MDR regulation for user facilities and manufacturers, published in the *Federal Register on December 11, 1995*, addresses the comments received by FDA on the November 29, 1991, tentative final regulation and the changes mandated by the Amendments of 1992.

Appendix C

Modernization Act Changes: Effective: February 19, 1998

User Facilities

The identity of user facilities that are submitting MDR reports is protected from disclosure except in connection with:

1) certain actions brought to enforce device requirements under the FFD&C Act; or

2) a communication to a manufacturer of a device that is the subject of a report to FDA of death, serious illness or injury, or other significant adverse experience.

As of July 31, 1996, all manufacturers, including foreign manufacturers, are subject to all requirements of *21 CFR Part 803* (MDR Reporting) including, but not limited to:

- the requirements for written MDR procedures (§803.17),
- MDR event files (§803.18),
- individual adverse event reports (§803.50 and §803.52),
- fiveday MDR reports (§803.53),
- the regulations now in effect, and
- will remain in effect during the stay, permit foreign manufacturers to:

- *register* their companies using Form FDA 2891, "Medical Device Establishment Registration," [§807.40(a)], and

- submit *premarket notifications* [510(k)s] (§807.81).

These regulations also require foreign manufacturers to list their devices on Form FDA 2892, medical "Device Listing," [§807.40(b)]. (Refer to the "Reporting for Foreign Manufacturer" section for the correct version of §807.40.)

TABLE 1 - Summary of Reporting Requirements for Manufacturers

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturer	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500a	FDA	Within 30 calendar days from becoming aware of an event
Manufacturer	5-day reports on events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA	Form FDA 3500A	FDA	Within 5 work days from becoming aware of an event

Appendix C

Releasable MDR Information

CDRH has made information received by FDA concerning medical devices that are in commercial distribution available to the public.

- *Releasable MDR Data Files*
- *Medical Device Tracking*
- *Postmarket Surveillance Studies*
- *MAUDE Data Files*

The post market reporting requirements of 21 CFR Part 803 (Medical Device Reporting) and 21 CFR Part 806 (Reports of Corrections and Removals) operate under the reporting requirements of section 519 of the Act (21 U.S.C. 360i]. The scope of the reporting requirements are limited to what sponsors/manufacturers or importers are required to provide FDA to assure a subject device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. I know of no text in the Act's section on Records and Reports on Devices that prohibits a voluntary warning associated with a report made to the Agency pursuant to section 519 of the Act. To the contrary, the agency's enforcement policy described in 21 CFR Part 7 would urge manufacturers to initiate a voluntary removal or correction of marketed violative products. The enforcement policy serves to enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

Appendix C

I hope this response clarifies how our premarket and postmarket reporting programs operate in terms of conveying important information and warnings about medical devices to FDA and to those who use the medical devices.

Sincerely yours,

s/ Casper E. Uldriks
Casper E. Uldriks
Special Assistant to the Director
Office of Compliance
Center for Devices and
Radiological Health

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturer	Baseline reports to identify and provide basic data on each device that is subject of an MDR report. At this time, FDA has stayed the requirement for denominator data requested in Part II, Items 15 and 16 on Form 3417.	Form FDA 3417	FDA	With 30 calendar, and 5 work day reports when device or device family is reported for the first time. Interim and annual updates are also required if any baseline information changes after initial submission.
Manufacturer	Annual Certification	Form FDA 3381	FDA	Coincide with firm's annual registration dates.

TABLE 2. - Summary of Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days
User Facility	Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days
User Facility	Annual reports death & serious injury	Form FDA 3419	FDA	January 1

(2)

No. 05-682

In the Supreme Court of the United States

JACK MCMULLEN AND BARBARA MCMULLEN,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a), which preempts state-law requirements with respect to medical devices that are "different from, or in addition to" federal requirements, preempts a state common-law action against a medical-device manufacturer that would impose a post-sale duty to warn when no such federal requirement exists.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

TABLE OF CONTENTS

TABLE OF CONTENTS – continued

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES – continued

Page(s)

Statutes, Rules, and Regulations

TABLE OF AUTHORITIES – continued

BRIEF FOR THE RESPONDENT IN OPPOSITION

The only question presented by this case is whether Section 360k(a) of the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, preempts a state common-law action that would impose a post-sale duty to warn on device manufacturers when no parallel federal duty to warn exists. There is no circuit conflict on this issue; indeed, petitioners concede that the issue "has not really been directly addressed by the circuit courts." Pet. 20. Even though the issue may not have been addressed directly prior to this case, the court of appeals was plainly correct in concluding that, under this Court's precedents, such a claim is preempted.

Seeking to bolster their petition for certiorari, petitioners allude to two circuit splits on issues regarding the proper interpretation of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), which are tangentially related to the issue presented here. This case does not implicate those splits, however, which are in any event shallow, increasingly stale, and likely to disappear even without this Court's intervention.

Thus, because there is no conflict among the circuits regarding the question presented, and because that question was correctly decided by the court of appeals, there is no reason for the Court to grant certiorari in this case.

STATEMENT

A. The regulatory structure of the Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device tech-

nology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA—in *Lohr* and, more recently, in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state-law tort actions challenging the design, manufacture, or labeling of "Class III" devices (*i.e.*, those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "premarket notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492–494.

Explicitly differentiating the minimal 510(k) notification process, at issue in *Lohr*, from the far more exacting premarket approval (PMA) process at issue here, the *Lohr* Court noted that "[t]he § 510(k) notification process is by no means comparable to the PMA process." *Id.* at 478–479. Thus, "[b]efore a new Class III device may be introduced to the market" via the PMA process,

> the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review. *Id.* at 479. Because the device at issue in *Lohr* had been marketed "without running the gauntlet of the PMA process," *id.* at 494, the *Lohr* Court never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one must engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that are arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common-law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504–505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506–507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process—which "is focused on *equivalence*, not safety" (*id.* at 493 (emphasis in original) (internal quotation omitted)) and which does "not 'require'" a medical device "to take any particular form for any particular reason"

(*ibid.*)—did not preempt the state-law claims raised by the Lohrs.

In the years since *Lohr*, a clear and growing consensus has emerged that, under the analytical framework laid out in that decision, FDA approval of a medical device through the PMA process preempts conflicting state-law claims arising from the design, manufacture, distribution, and labeling of such a device. Every court of appeals to have considered the issue in the past seven years has concluded, as did the Seventh Circuit below, that the FDA's rigorous PMA process establishes device-specific federal requirements that, pursuant to 21 U.S.C. § 360k(a), preempt state common-law damages claims that would effectively create state requirements "different from" or "in addition to" the federal requirements.[1] As we discuss below (see Part I.B, *infra*), petitioners acknowledge the existence of preemption in the PMA context and have waived any challenge to this established interpretation of § 360k(a).

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not

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[1] See, *e.g.*, Pet. App. 9a–10a; *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir.), *cert. denied sub nom. Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 171–177 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc), *cert. denied*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 584–585 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 224-27 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911–914 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997).